K003384

NOV 2 4 2000

VI. 510(k) Summary of Safety and Effectiveness

1. Submission Applicant & Correspondent:

Name: Osteotech, Inc.
Address: 51 James Way
Eatontown, NJ 07724
Phone No.: (732) 542-2800
Contact Person: Kim Thurman

2. Name of Device:

Trade/Proprietary/Model Name: Versalok® Low Back Fixation System (VERSALOK)
Common or Usual Name: Posterior Spinal Fixation Device
Classification Names: Spinal Interlaminal Fixation Orthosis; Spondylolisthesis Spinal Fixation Device System; Pedicle Screw Spinal System

3. Devices to Which New Device is Substantially Equivalent:

The Versalink® System, with the addition of the titanium rod-to-rod couplers is substantially equivalent, to the current stainless steel Versalok System that includes rod-to-rod couplers (K980496) and titanium components (K990708).

4. Device Description:

The Versalok® Low Back Fixation System is a posterior spinal fixation device that consists of rods, bone screws to anchor the rods to the spine, and couplers designed to form a transverse connection between the rods in a spinal construct.

5. Intended Use/Indications

The Versalok® Low Back Fixation System is intended to provide temporary maintenance and support of the correction during the time normally needed for the fusion mass to mature.

1) A construct with screws attached to the pedicles of the lumbar and sacral spine (L3 to S1) and autogenous bone graft may be used only for the treatment of severe spondylolisthesis (grade 3 or 4) at the fifth lumbar – first sacral (L5-S1) vertebral joint (see warning below). The device is intended to be implanted using a posterior surgical approach and removed after the development of a solid fusion mass.

2) When not used as a pedicle screw fixation system, various combinations of the VERSALOK components are also indicated to provide temporary stability of the thoracic, thoracolumbar, or lumbar spine (T1 to S1) during bony fusion healing secondary to:

a) Unstable spinal fractures (such as fracture dislocations) or instability secondary to spinal tumors;
b) Degenerative disk diseases of the spine (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies);
c) Spinal curvatures (such as idiopathic scoliosis, neuromuscular scoliosis/kyphoscoliosis with associated paralysis or spasticity, and secondary to spinal fractures) which are:
   - Progressive, despite other forms of treatment,
   - Detrimental to cardiopulmonary function,
   - Interfering with spinal mechanics or causing severe back pain, or
   - Cosmetically unacceptable, progressive, and painful.

For the above indications, use of spinal fixation instrumentation in children has been reported.[1,2] Children should have adequate bony and soft tissue maturity to undergo implantation but need not have reached skeletal maturity.

3) The Versalok® Low Back Fixation System is also a pedicle screw system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

6. Performance Data

Mechanical testing of the Versalok® System with the titanium Versalink couplers was performed in accordance with the ASTM Standard for testing spinal implant devices. The test results demonstrated that the mechanical performance characteristics of the Versalok System with the titanium couplers are comparable to those of the predicate devices.

1. Heftl, F.L. and McMaster, J.J.: The Effect of the Adolescent Growth Spurt on Early Posterior Spinal Fusion in Infantile and Juvenile Idiopathic Scoliosis. *J. Bone and Joint Surg.* 1983;65-B:247-254.

2. Moe, J.H., Kharrat, K., et al.: Harrington Instrumentation Without Fusion Plus External Orthotic Support the Treatment of Difficult Curvature Problems in Young Children. *Clin. Ortho. Rel. Res.* 1984; (185):35-45.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 4 2000

Ms. Kim Thurman
Regulatory Affairs Associate
Osteotech, Inc.
51 James Way
Eatontown, New Jersey 07724

Re: K003384
Trade Name: VersaLink® Titanium Rod-To-Rod Coupler
Regulatory Class: II
Product Code: MNH, MNI, KWP, KWQ
Dated: October 27, 2000
Received: October 31, 2000

Dear Ms. Thurman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Acting Director
Division of General, Restorative
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 2

This section provides for an Indications for Use Statement.

510(k) Number (if known): K003384

Device Name: Versalok® Low Back Fixation System

Indications for Use:

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A construct with screws attached to the pedicles of the lumbar and sacral spine (L3 to S1) and autogenous bone graft may be used only for the treatment of severe spondylolisthesis (grade 3 or 4) at the fifth lumbar – first sacral (L5-S1) vertebral joint (see warning below). The device is intended to be implanted using a posterior surgical approach and removed after the development of a solid fusion mass.

When not used as a pedicle screw fixation system, various combinations of the VERSALOK components are also indicated to provide temporary stability of the thoracic, thoracolumbar, or lumbar spine (T1 to S1) during bony fusion healing secondary to:

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(Division Sign-Off)
Division of General Restorative Devices

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objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

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PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ——— OR Over-The Counter Use ———
(per 21 CFR 801.109)

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for Mark N Milhous

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Division of General Restorative Devices

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1. Heftl, F.L. and McMaster, J.J.: The Effect of the Adolescent Growth Spurt on Early Posterior Spinal Fusion in Infantile and Juvenile Idiopathic Scoliosis. *J. Bone and Joint Surg.* 1983;65-B:247-254.

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